



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,711	07/27/2001	Rathbun Rhodes	1146-8	8240
20995	7590	02/14/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			NASSER, ROBERT L	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3736	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 09/916,711	Applicant(s) RHODES ET AL.	
	Examiner Robert L. Nasser	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-15 and 22-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-15, 22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/2005 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-10, 12-15, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al 6001067 in view of McIvor et al 6360888. Shults et al shows a glucose sensing device including a housing made from polyethylene, (see column 9, lines 35-36), where the housing includes a sensing area having a working reference and counter electrode 20, 21, and 22, and a multi-layer membrane over the electrode area. The area of the counter and working electrodes appears to be the same. In addition, the device includes a cell disruptive member, i.e. angiogenic layer around its periphery. However, McIvor shows in figure 15, a 3 electrode system for measuring glucose concentration, where the counter electrode is made larger than the working. Therefore, it would have been obvious to modify Shults et al to use such an arrangement of working and counter electrodes, as it is merely the substitution of one known equivalent sensor arrangement for another. The examiner notes that Nagata

Art Unit: 3736

does not disclose the relative sizes of the electrodes. However, it is the examiner's position that the exact relative sizes within the parameters given in column 9, lines 1-19 of Mclvor would have been a mere matter of design choice for one skilled in the art. The multi-layer membrane includes (from farther away to adjacent to electrodes) an angiogenic layer which is equivalent to the disclosed cell disruptive domain, a second layer which is the bioprotective layer, which is equivalent to the cell impermeable domain, then an enzyme membrane comprised of a resistance layer, an enzyme layer, an interference layer, and a electrolyte (i.e. hydrogel layer). The examiner notes that with respect to claim 6, the first domain is the angiogenic layer and the bioprotective layer. With respect to claim 7, the resistance layer is the second domain and excludes glucose. With respect to claims 8 and 9, the enzyme layer is the third domain. Both the working and counter electrodes are made from platinum (see column 9, line 62-column 10, line 2). The device of Shults is implanted. Shults further teaches the recited method.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of Mclvor et al as applied to claims 1, 2, 5-10, 12-15, and 22-33 above, and further in view of Schulman et al 6119028. Shults does not teach a material for the resistance layer. However, Schulman shows a membrane 24 that behaves in the same manner of the resistance layer. Membrane 24 of Schulman is made from silicone, which is disclosed to be the material used for the oxygen antenna domain. Hence, it would have been obvious to modify Shults to make the resistance layer from silicone, as it is merely the substitution of one known material for another. Hence,

membrane 24 is an oxygen antenna. With respect to claim 7, membrane 24 is a glucose exclusion membrane

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of McIvor et al as applied to claims 1,2, 5-10, 12-15, and 22-33 above, and further in view of Ward et al et al. Ward et al shows an analyte sensing device with a ceramic housing. Hence, it would have been obvious to modify Shults et al to use ceramic, as it is merely the substitution of one known equivalent material for another.

Applicant's arguments filed 9/30/2005 have been fully considered but they are deemed moot in view of the new grounds of rejection.

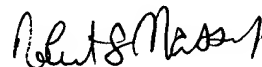
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
February 4, 2006



ROBERT L. NASSER
PRIMARY EXAMINER